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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CONNETICS CORP. SECURITIES LITIGATION

Case No. C 07-02940 SI

REPLY MEMORANDUM IN SUPPORT OF REQUEST FOR JUDICIAL NOTICE BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS

Date: October 19, 2007
Time: 9:00 a.m.
Dept: Courtroom 10, 19th Floor
Judge: Honorable Susan Illston

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I. INTRODUCTION

Plaintiff admits that the Court may take judicial notice of all but six of the 41 exhibits submitted by Connetics in support of its motion to dismiss. The remaining six exhibits – four public records from the FDA (Exhibits 30 to 33) and two summary exhibits (Exhibits 39 and 40) – are also subject to judicial notice. The FDA records fall squarely within the ambit of Rule 201 of the Federal Rules of Evidence. The contents of these documents are capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201. The two summary exhibits may also be considered. They are accurate summaries of other voluminous and judicially noticeable facts. There is no legitimate reason to ignore them. *See* Fed. R. Evid. 1006 (allowing summaries of voluminous documents).

Plaintiff ignores the governing legal standard and instead argues that the Court should not consider the FDA public records because, according to plaintiff, they are not "central" to its claim. RJN Opp. at 9. However, the law does not impose a "centrality" test. In any event, the FDA public records go to the heart of plaintiff's claims because they show that the FDA approved dermal products with benzoyl peroxide even though that substance "induced skin tumors in transgenic Tg.AC mice." Steskal Decl. Ex. 30. Connetics was aware of, and relied on, the FDA's past decisions relating to such products when it projected that Velac could be approved by the FDA. *Id.* Ex. 1, at 6. The FDA public records refute any inference that defendants intended to mislead investors about Velac's prospects for approval. *See In re Vertex Pharms., Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 352 (D. Mass. 2005) (taking judicial notice of FDA public records and holding that undisclosed preclinical animal test did not foreclose prospects of FDA approval because other products had been approved that showed toxicity in same preclinical test).

Plaintiff expends most of its opposition arguing that although the Court may take judicial notice of many of the exhibits, it should then disregard those exhibits whenever plaintiff asserts in conclusory fashion that the facts are "hotly contested." RJN Opp. at 4. Not surprisingly, plaintiff's nonsensical argument is contrary to the law. *Tellabs* makes clear that a court ***must*** consider ***all the facts alleged*** including, "in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs v. Makor Issues &*

Rights, Ltd., 127 S. Ct. 2499, 2509 (2007). In addition, "in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court ***must take into account plausible opposing inferences***," that is, "plausible nonculpable explanations for defendants' conduct." *Id.* at 2509-10 (emphasis added). When undertaking this "inherently comparative" inquiry, a court must weigh competing inferences and determine whether plaintiff has met its burden of pleading a "cogent and compelling" inference of scienter, which is an inference that is "more than merely plausible or reasonable." *Id.* at 2504-05, 2510.

Plaintiff's argument would foreclose the very analysis that is compelled by the Reform Act and *Tellabs*. Whereas the Reform Act and *Tellabs* require a court to consider judicially noticeable facts and draw inferences from those facts that are favorable to the defendants, plaintiff argues that this Court should disregard such facts whenever defendant disagrees with (*i.e.*, "disputes") those inferences. RJN Opp. at 4. If accepted, the Court would be left with nothing to consider but the "facts" plaintiff selectively highlights and the inferences that plaintiff urges. That is precisely the legal standard that the Reform Act and *Tellabs* rejected. Moreover, the Reform Act is clear that a plaintiff cannot allege a securities fraud claim merely by stating in conclusory fashion, as plaintiff does here, that a statement or fact is "false" or "hotly contested." *Id*. Rather, a plaintiff must plead facts with particularity demonstrating the reasons why the statement or fact is false. 15 U.S.C. § 78u-4(b)(1); *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 984 (9th Cir. 1999) ("[W]e read the statutory command that a plaintiff plead all the 'facts' with 'particularity' to mean that a plaintiff must provide a list of all relevant circumstances in great detail").

Plaintiff is also wrong when it contends that the Court cannot consider the documents at issue for the truth. RJN Opp. at 1. This proposition is directly contradicted by the very authority relied on by plaintiff in its opposition. *See In re CV Therapeutics, Inc. Sec. Litig.*, 2004 WL 1753251, *12 (N.D. Cal. Aug. 5, 2004) ("Finally, plaintiffs argue that the Court cannot consider any documents for the 'truth of their contents.' The Court does not restrict its taking of judicial notice in this way.") (citations omitted); *see also* Fed. R. Evid. 803(8) (public records are not hearsay and may be considered for truth). In any event, even if the Court does not consider

the documents at issue for the truth, the Court must consider the documents when determining whether plaintiff has pleaded a "cogent and compelling" inference of scienter. That means that if the contents of a judicially noticeable document or a document cited in the complaint refutes an inference of scienter, the Court must consider that document and dismiss plaintiff's complaint. *See Tellabs*, 127 S. Ct. at 2509-10 (requiring court to examine judicially noticeable documents and documents incorporated by reference and to engage in comparative analysis that credits inferences favorable to defendants); *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002) (holding that court "must consider . . . inferences unfavorable to the plaintiffs" and dismissing complaint where allegations negated a strong inference of scienter); *In re Applied Micro Circuits Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, *12 (S.D. Cal. Oct. 3, 2002) (holding that court must consider entire contents of SEC filings selectively quoted in complaint for purpose of drawing inferences relating to plaintiff's allegations).

II. THE COURT SHOULD TAKE JUDICIAL NOTICE OF FDA RECORDS

Plaintiff objects to Exhibits 30 to 33, public records available from the FDA's website. However, plaintiff fails to articulate any reason why the Court should not take judicial notice of these records under Rule 201. Exhibits 30 to 33 are neither subject to reasonable dispute nor can their accuracy be questioned. The law is clear that courts routinely take notice of records and reports of administrative bodies, such as the FDA. *See Metro Pub., Ltd. v. San Jose Mercury News*, 987 F.2d 637, 641 n.3 (9th Cir. 1993) (taking judicial notice of trademark registrations); *Interstate Natural Gas Co. v. Southern California Gas Co.*, 209 F.2d 380, 384-85 (9th Cir. 1953) (taking judicial notice of contract and rates filed with federal agency); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of FDA report posted on FDA website).

Plaintiff wrongly contends that the court cannot take judicial notice of Exhibits 30 through 33 because they are not "central" to plaintiff's claim or "referenced" in the complaint. RJN Opp. at 9. That is not the standard. Rather, a court can take judicial notice of FDA public records in a securities fraud case because such records are available to and relied upon by the investing public and provide context for plaintiff's allegations. *See Vertex Pharms.*, 357 F. Supp. 2d at 352 n.4

(taking judicial notice of FDA public records); *In re Guidant Corp. Sec. Litig.*, 2006 WL 2538374, *9 n.20 (S.D. Ind. Nov. 8, 2004) (same). Notably, plaintiff does not dispute that the Court can take judicial notice of similar documents under the same legal doctrine, including the FDA's Manual of Policies and Procedures (Exhibits 28 and 29) and various analyst reports (Exhibits 35 through 37). Given the lack of any objection to such documents, it is clear that plaintiff's objections here are not based on principle, but on a thinly cloaked desire to distract the Court from considering public records that are devastating to plaintiff's allegations of fraud.

In any event, plaintiff is wrong when it argues that FDA records are not "central" to its claim. The gravaman of plaintiff's claim is that defendants made optimistic statements about Velac's prospect for approval when, according to plaintiff, they knew all along that approval could not be obtained. The FDA records establish that defendants reasonably believed that Velac could be approved despite the results of the Tg.AC mouse study. For example, Exhibits 30 is the FDA approval label for BenzaClin (which includes benzoyl peroxide):

> **BenzaClin™ Topical Gel** **Rx Only**
> (clindamycin - benzoyl peroxide gel)
>
> **Topical Gel: clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%)**
> **For Dermatological Use Only - Not for Ophthalmic Use**
> ***Reconstitute Before Dispensing***
>
> …
>
> **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.
>
> Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

This FDA public record demonstrates that dermal products that include benzoyl peroxide have been approved by the FDA despite adverse Tg.AC test results: "Benzoyl peroxide . . . induced skin tumors in transgenic Tg.AC mice." Far from foreclosing the possibility of FDA approval for BenzaClin, the adverse Tg.AC test results were simply included as part of the BenzaClin label.

Other courts have taken judicial notice of similar records and held that they are highly relevant in evaluating whether a plaintiff has met its burden of pleading a strong inference of

scienter. For example, in *Vertex Pharms.*, the plaintiff alleged that defendants misrepresented the prospects for a drug's approval and made false and misleading statements regarding the results of Phase I and II clinical studies because the defendants failed to disclose that preclinical animal tests showed that the drug was "dangerously toxic." The court dismissed plaintiff's complaint:

> [T]he allegation that the defendants were aware that preclinical testing demonstrated a toxicity problem with VX-745 by March of 1999 is not in itself sufficient to demonstrate scienter. The fact that a drug has a certain toxicity level does not necessarily doom the drug's commercial prospects. As defendants point out, many drugs currently on the market are toxic depending on dosage levels and concentrations. Defendants note that other drugs (such as Lipitor and Zocor) have been found in animal studies to have toxic effects on the CNS in certain dosages, yet have been approved by the FDA. *See Def.'s Exh.* I, J. Thus, defendants' knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to indicate "a mental state embracing intent to deceive, manipulate, or defraud.

357 F. Supp. 2d at 352 (case citation omitted). The same analysis applies here. The fact that Velac showed a positive response in the Tg.AC model did not "doom the drug's commercial prospects." *Id.* As shown by the FDA public records relating to BenzaClin, other dermal products have shown a positive result in that model but were nonetheless approved by the FDA. As such, the FDA documents are exactly the type of judicially noticeable records that the Court is required to consider under *Tellabs* because they refute an inference of scienter.

Plaintiff is also wrong when it argues that the Court should not consider the contents of Exhibits 30 through 33 because the documents are not "referenced" in its complaint. RJN Opp. at 9. As shown, that fact has no legal significance because a court is required to consider judicially noticeable documents, even if not referenced in the complaint. *Tellabs*, 127 S. Ct. at 2509. In any event, the complaint quotes at length from documents that demonstrate that (1) defendants were aware that the FDA had approved dermal products with benzoyl peroxide even though that compound "induced skin tumors in transgenic Tg.AC mice" and (2) defendants relied on those FDA decisions when they determined that Velac could be approved. For example, the complaint specifically calls out, quotes from, and relies on Connetics' April 26, 2005 conference call regarding the Tg.AC mouse study. *See* AC ¶¶ 261-265. During that conference call, Connetics specifically referred to drugs such as BenzaClin that also have had positive Tg.AC test results to explain why they believed Velac could be approved. Ex. 1 at 6, 24; s*ee infra* at 9.

Plaintiff attempts to avoid the import of the April 26, 2005 conference call by literally deleting from the quotations in its complaint the portions that refer to the FDA approval of dermal products with benzoyl peroxide. *Compare* AC ¶ 261 (" . . . ") *with* Ex. 1, at 6 ("benzoyl peroxide, a commonly used OTC acne product and an ingredient in several prescription acne products, has Rx labeling that notes a positive result in this model") . However, despite plaintiff's self-serving attempt to edit the statement, the law is clear that when a plaintiff selectively quotes from a document, the court must consider the entire document. *See Osher v. JNI Corp.*, 308 F. Supp. 2d 1168, 1186 (S.D. Cal. 2004), *aff'd in relevant part*, 183 Fed. Appx. 604 (9th Cir. 2006) (court must consider full document, not just portions plaintiff "selectively quote"); *Reiger v. Altris Software, Inc.*, 1999 WL 540893, *2 (S.D. Cal. Apr. 30, 1999) ("the court may consider the full text of those documents, even when the complaint quotes only selected portions."); *In re Harmonic, Inc. Sec. Litig.*, 163 F. Supp. 2d 1079, 1084 (N.D. Cal. 2001) (defendants may "attach to a 12(b)(6) motion the documents referred to in the complaint to show that they do not support plaintiff's claim.").

Plaintiff also attempts to distract the Court from the import of the FDA public records by arguing that the facts relating to the approval of benzoyl peroxide are "highly disputed." RJN Opp. at 10. However, plaintiff never explains what exactly it disputes about those facts, nor does it make any allegations in its complaint demonstrating with the requisite particularity that defendants misrepresented those facts. For instance, plaintiff does not allege – nor could it – that dermal products with benzoyl peroxide were not approved by the FDA despite the fact that benzoyl peroxide "induced skin tumors in transgenic Tg.AC mice." Plaintiff also does not allege – nor could it – that defendants were unaware of the FDA's decision to approve those products and did not rely on that decision when they projected that Velac could be approved. At bottom, plaintiff's quarrel is not with the judicially noticeable facts, but with the inferences that defendants draw from those facts: namely, that defendants reasonably concluded that Velac might be approved. Under *Tellabs*, the Court must consider those inferences, and dismiss the complaint where (as here) it eviscerates any "cogent and compelling" inference of scienter. *See Vertex Pharms.*, 357 F. Supp. 2d at 352.

III. THE COURT SHOULD TAKE JUDICIAL NOTICE OF SUMMARY EXHIBITS

Plaintiff also objects to Exhibits 39 and 40. These are summaries of what plaintiff acknowledges are judicially noticeable facts. Such summaries are offered merely as a convenience to the Court, and the Court may properly consider them. *See, e.g.*, *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1218 (S.D. Cal. 2001) (taking judicial notice of chart summarizing company's risk disclosures); *see also* Fed. R. Evid. 1006.

Exhibit 39 is a table summarizing defendants' stock sales and holdings of Connetics stock during the period of July 1, 2001 to July 9, 2006. It is based on judicially noticeable documents, principally Forms 4 filed by the individual Connetics defendants. *See* Exs. 24-26. Plaintiff does not contest the accuracy of Exhibit 39, but rather takes issue with its relevance, arguing that it is improper to include underwater options in calculating the defendants' holdings. However, plaintiff cites absolutely no authority whatsoever for this novel proposition. Rather, the law is clear than when evaluating a defendant's stock sales, a court must compare those sales to the defendant's total stock holdings, which includes exercisable stock options. *Silicon Graphics*, 183 F.3d at 986-87. There is no basis in the case law to exclude so-called underwater stock options from that analysis. Moreover, plaintiff's proposed rule makes no sense. A defendant would have the same motivation to increase the share price (so that the options were no longer underwater) regardless. In any event, plaintiff never alleges what defendant's total holdings would be if so-called underwater stock options were excluded. Exhibit 39 is properly considered because it is based on documents that plaintiff admits are judicially noticeable, and there is no dispute that it is an accurate summary of these voluminous documents.

Exhibit 40 is a table summarizing some of the meaningful cautionary language related to Velac gel. It is based on judicially noticeable documents, namely public filings and statements. *See* Exs. 1, 3-8, 10-12, 17-18. Plaintiff's objection to this exhibit ignores that, with respect to forward-looking statements, the Reform Act explicitly provides that courts ***must*** examine the contents of public statements and the relevant cautionary language that applies to those statements. 15 U.S.C. § 78u-5(e) . Moreover, with respect to oral statements during analyst calls, courts ***must*** examine the cautionary statements that are contained in written documents and SEC

filings referenced during the analyst calls. 15 U.S.C. § 78u-5(c)(2). Exhibit 40 properly excerpts the relevant cautionary language so that the Court can readily evaluate plaintiff's allegation that defendants intentionally deceived investors about Velac's prospects for FDA approval. As shown in Exhibit 40, defendants never promised that Velac would be approved, but rather repeatedly warned that FDA approval was uncertain and may be denied.

IV. THE COURT SHOULD CONSIDER JUDICIALLY NOTICEABLE FACTS IN RULING ON THE MOTION TO DISMISS

The remainder of plaintiff's opposition is spent arguing not over whether the Court may take judicial notice of the exhibits – it concedes that it can – but over "defendants' characterizations" of the documents and alleged "improper use of such documents." RJN Opp. at 1. As shown above, however, this argument is a red herring. The law requires the Court to review the documents and then consider inferences that can be drawn from those documents that refute plaintiff's allegation of scienter. *See Tellabs*, 127 S. Ct. at 2509-11. Plaintiff cannot foreclose that analysis merely by arguing that it "opposes defendants' characterization" of the document, or asserting that defendants are somehow misusing the documents by arguing that they eviscerate scienter. RJN Opp. at 1. Even before *Tellabs*, the Ninth Circuit rejected the argument that a court had to accept a plaintiff's characterization of the facts and could not consider a defendant's characterization when ruling on a motion to dismiss. *See Gompper*, 298 F.3d at 897. Now, after *Tellabs*, the law is clear that a court must consider and weigh a defendant's characterization of factual allegations and judicially noticeable documents when deciding whether a plaintiff has pleaded a "cogent and compelling" inference of scienter. *See Tellabs*, 127 S. Ct. at 2509-11.

For these reasons, the Court must take judicial notice of Exhibits 1, 2, 7, 8, 13-16 and 19 and draw inferences from those documents that negate scienter under *Tellabs*.

A. Exhibit 1– Transcript of Connetics' April 26, 2005 Call

Exhibit 1 is a transcript of Connetics' April 26, 2005 conference call. Plaintiff relies on this transcript in the complaint and admits that the Court may take judicial notice of it. AC ¶¶ 78-

79, 261-65; *see also* RJN Opp. at 4.[1] In that transcript, Connetics reports several facts that explain its actions and negate any inference that defendants knew at the time that the FDA would deny approval for Velac, including:

- "We conducted one of our preclinical studies in a transgenic mouse model. And in that study there was a positive response to our product. At the time, ***we carefully analyzed the results with a panel of leading experts in this model and leading toxicologists. The outcome of that was that the experts advised us that this mouse model is known to have limitations. And they concluded that the positive response was a result of one of these limitations of the model.***" Steskal Decl. Ex. 1 at 5 (emphasis added).

- "Their advice is supported in fact, by other products which have had a positive finding in this model, resulting in a clinical hold only to be released later based upon submission of additional data. And in fact, ***benzoyl peroxide, a commonly used [over-the-counter] acne product and an ingredient in several prescription acne products has Rx labeling that notes a positive result in [a transgenic mouse] model***." *Id.* at 5-6 (emphasis added).

- "***Because up to this point [the] FDA had not raised this issue with us, we were surprised to receive this information.*** However, we are in discussions with them on their questions. And we expect to submit additional information well before the PDUFA date which further supports our original conclusion." *Id.* at 6 (emphasis added).

- "I would point out that as a rule, ***we do not feel it is appropriate frankly, to provide regular updates on our discussions with [the] FDA***." *Id.* (emphasis added).

Although plaintiff cites extensively from this conference call transcript in its complaint (AC ¶¶ 261-64), plaintiff now argues that the Court should ignore much of the transcript because, according to plaintiff, defendants' statements are "fabrications." RJN Opp. at 4. However, plaintiff pleads no facts – much less facts with particularity as required by the Reform Act – demonstrating that any of the statements are false or misleading. For instance, plaintiff does not allege that the expert panel did not conclude that the positive response in the mouse model "was a result of one of [the] limitations of the model," *i.e.*, that it was a false positive. AC ¶ 261. Likewise, as shown, plaintiff does not allege that the FDA has not approved dermal products that had a positive response in the Tg.AC mouse model. In the absence of particularized allegations

[1] Although plaintiff asserts that the authenticity of the transcript is in question at this point, it cannot both rely on and quote this transcript in its complaint and at the same time dispute its authenticity. *See Osher*, 308 F. Supp. 2d at 1186 (court must consider full document, not portion plaintiff "selectively quoted"); *Reiger*, 1999 WL 540893, at *2 ("the court may consider the full text of those documents, even when the complaint quotes only selected portions"); *In re Harmonic*, 163 F. Supp. 2d at 1086 (defendants may "attach to a 12(b)(6) motion the documents referred to in the complaint to show that they do not support plaintiff's claim").

demonstrating falsity under the Reform Act, the Court must accept the statements as true and draw inferences in defendants' favor. Here, the facts demonstrate that defendants reasonably believed that Velac could be approved by the FDA despite the positive response in the Tg.AC mouse model. *See Tellabs*, 127 S. Ct. at 2509-10 (holding that courts must engage in comparative analysis that credits inferences favorable to defendants); *Applied Micro Circuits Corp.*, 2002 U.S. Dist. LEXIS 22403, at *12 (where plaintiff "refer[s] to [] SEC filings in its amended complaint, [] it cannot therefore selectively argue that Defendants' cannot rely on the same material").

B. Exhibit 2 – Transgenic Mouse Models Article

Exhibit 2 is an article titled "Transgenic Mouse Models: Their Role in Carcinogen Identification." Plaintiff quotes this document and relies on it in the complaint to show that mouse studies make "correct" calls 77 to 81 percent of the time (and, by inference, make "incorrect" calls 19 to 23 percent of the time). AC ¶ 56. Plaintiff further agrees that the Court may take judicial notice of the fact that transgenic mice are engineered so that tumors will develop more quickly. RJN Opp. at 5. However, plaintiff takes issue in its opposition with the following statements that are also included within the article:

- "Overall, the transgenic models performed well, but important issues of validation and standardization need further attention to permit their regulatory acceptance and use in human risk assessment." Steskal Decl. Ex. 2 at 3.
- "Although they have great promise, transgenic models also have actual or potential limitations for use in a carcinogen identification effort. For example, many current transgenic models (including those evaluated here) have mutations in only one pathway that may, or may not, be relevant to human cancer processes for a given chemical. In addition, the specific gene defect may influence tumor development and type, increasing the difficulty of modeling the human response." *Id.* at 5.

But again, there is nothing in the complaint that disputes these facts. AC ¶¶ 54, 56. Indeed, plaintiff itself relies on the same article for its truth. *Id.* ¶ 56. Moreover, Exhibit 2 demonstrates that there are known limitations to the transgenic mouse model, and positive results in Tg.AC mice may not be relevant to human cancer processes. Exhibit 2 is particularly relevant here because an expert panel told Connetics that Velac's positive response in the mouse model "was a result of one of these limitations of the model." AC ¶ 261. Thus, the Exhibit fully

corroborates the conclusions of the expert panel, namely, that the results of the mouse test were a false positive. The Court must take judicial notice of these facts in evaluating whether plaintiff has alleged a "cogent and compelling" inference of scienter. *See Tellabs*, 127 S. Ct. at 2509.

C. Exhibits 7, 8, 13-16 and 19 – SEC Filings

Finally, plaintiff argues that the Court may not consider SEC filings that plaintiff itself cites and relies on in its complaint. However, here again, plaintiff alleges disputes where there are none and asks the Court to ignore judicially noticeable documents in evaluating scienter.

Exhibit 8. Plaintiff does not assert that Exhibit 8 – a May 14, 2002 press release from Connetics – contains any false or misleading statements. AC ¶¶ 52-80; *see also* AC ¶ 41 (quoting press release). There is absolutely no allegation in the complaint that the statement that "clinical studies in more than 700 patients in Europe … have shown Velac gel to be safe and effective as leading topical treatments," was either false or misleading. *See* Ex. 8; AC ¶¶ 52-80. In fact, those statements were made before the class period and thus could not form the basis of any claim. Moreover, the European clinical tests showing that Velac was safe for human use are highly relevant in assessing whether plaintiff has alleged a "cogent and compelling" case that defendants in fact knew that Velac could never be approved. *See In re Invision Tech., Inc. Sec. Lit.*, 2006 WL 538752, *2 (N.D. Cal. Jan. 24, 2006) (statements outside class period are not actionable but considered only in context of demonstrating "truth of falsity of Class Period statements"); *DeMarco*, 149 F. Supp. 2d at 1223 n.6 (statements before the class period "may have evidentiary relevance to the issue of scienter"). In fact, these European clinical test results are consistent with the results of the Phase III clinical trials in the United States which involved testing on 2,200 patients. AC ¶¶ 36, 44-48, 255; Steskal Decl. Ex. 6, at 6 & Ex. 7, at 10. Thus, the prior clinical studies in Europe, like the Phase III clinical trials in the United States, are relevant to the scienter of defendants. Those tests demonstrate that defendants had compelling reasons to be optimistic that Velac could be approved by the FDA.

Exhibit 7. Plaintiff likewise does not allege in its complaint that Exhibit 7—a July 25, 2006 Form 10-K/A SEC filing—contains any false or misleading statements. In fact, plaintiff repeatedly cites that filing for the truth. AC ¶¶ 130-32. Moreover, that Form 10-K/A was issued

after the end of the class period and thus cannot form the basis of plaintiff's fraud claim. AC ¶ 27 (class period ends on July 9, 2006); *see also Invision Tech.*, 2006 WL 538752, at *2; *DeMarco*, 149 F. Supp. 2d at 1223 n.6. Given these express allegations in the complaint, plaintiff cannot conceivably argue (as it now attempts to do in its brief) that the Form 10-K/A contains "false" factual assertions. In any event, there is no allegation in the complaint that disputes the fact that "until December 2005 the reports received [from Connetics' distributors] contained inaccuracies and inconsistencies that made them unreliable." Ex. 7 at 31; AC ¶¶ 109-120. In fact, despite the fact that Connetics publicly disclosed that it received inventory reports from its distributors, plaintiff never explains how Connetics could have engaged in fraudulent channel stuffing if those reports did not show a backlog of inventory.

Exhibits 13, 14, 16 and 19. Plaintiff fails to allege with any specificity that any statement contained or relied on in Exhibits 13, 14 and 19 was either false or misleading. AC ¶¶ 201-204, 217-220, 282-286. Instead, plaintiff block quotes from these press releases and generically alleges that these statements were "materially false and misleading" for unstated reasons purportedly having something to do with plaintiff's allegations of channel stuffing. *See, e.g.*, AC ¶¶ 204, 220, 286. This type of "puzzle pleading" is not sufficient to plead securities fraud under the Reform Act. 15 U.S.C. § 78u-4(b)(1)(B); *see also In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1075 (N.D. Cal. 2001) (this type of pleading "obfuscates rather than clarifies" and fails to "divine precisely which statements (or portion of statements) are alleged to be false or misleading, and the reason or reasons why each statement is false or misleading"). (quotation omitted)

In any case, the Court may take judicial notice of these press releases and consider them for the purpose of evaluating whether plaintiff's inference of scienter is cogent and compelling under *Tellabs*. In fact, there is nothing in the complaint that disputes any of the following:

- Connetics submitted an NDA application for Velac to the FDA in August 2004, which was accepted in October 2004. *See* Steskal Decl. Exs. 14-15.
- There is a user fee associated with an NDA application. *See id.* Ex. 15.
- Connetics paid $3.5 million to Yamanouchi Europe BV in conjunction with its submission of the Velac NDA to the FDA. *See id.* Exs. 14, 16.

- In Q4 2004, Connetics hired 66 sales professionals, more than doubling its sales force. *See id.* Ex. 16.

The Court may take judicial notice of these facts—and may draw inferences from them, including the reasonable inference that Connetics incurred substantial expenses in seeking FDA approval for Velac and preparing to launch Velac. Far from supporting an inference of fraud, these facts demonstrate that defendants actually believed that Velac could obtain FDA approval. *See Tellabs*, 127 S. Ct. at 2510; *see also In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (scienter dispelled by efforts to prepare product for launch).

V. THE COURT SHOULD TAKE JUDICIAL NOTICE OF EXHIBIT 42

Defendants also request judicial notice of Exhibit 42, which is attached to the Supplemental Declaration of Christopher Steskal. Exhibit 42 is a transcript of a January 25, 2005 conference call that was incorporated by reference in the complaint. AC ¶¶ 241-245. In its complaint, plaintiff engages in impermissible "puzzle pleading" by citing numerous statements and then alleging in conclusory fashion that the statements are "false or misleading." AC ¶ 146-332. In its opposition to the motion to dismiss, plaintiff reaches back to paragraph 242 of the complaint and quotes one such statement from the January 25, 2005 conference call. Opp. at 4, 11-12 (citing AC ¶¶ 242-245). However, plaintiff wrongly cites the statement out of context. Contrary to plaintiff's suggestion, defendants Wiggins and Higgans were not discussing whether Velac would be approved by the FDA during that call, but rather whether (if it were approved) it could compete against other products on the market. In particular, when an analyst asked about "potential competitors to Velac," defendant Wiggans stated that "we're very confidant in the data set we got." Supp. Steskal Dec. Ex. 42 at 17-18; *see also id.* at 3 ("[O]ur planning case is that there will be a competitive product for Velac but we have excellent data on Velac.").

To give context to the quoted statements, defendants request that the Court take judicial notice of Exhibit 42. *See Cooper v. Pickett*, 137 F.3d 616, 623 (9th Cir. 1997) (court may consider document referenced in complaint); *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994) (same). When read in context, the statements during the January 25, 2005 conference call show that defendants actually believed Velac could be brought to market and that they were making

plans and investing resources to do just that. *See Apple Computer*, 886 F.2d at 1118. Moreover, it is undisputed that the Phase III clinical trials and European clinical trials demonstrated the efficacy of Velac and provided ample reason to be confident in Velac's ability to compete. In any event, the law is clear that generalized assertions of corporate optimism (*e.g.*, "excellent results") are too vague and unspecific to be actionable under the securities laws. *See In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005); *see also In Re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 162 (D. Mass. 2007) ("Every company praises its products and its objectives, and these statements are nothing more than corporate puffery.").

VI. CONCLUSION

For the reasons stated herein and in defendants' Request for Judicial Notice, the Court should grant judicial notice of Exhibits 1 to 42 of the Declaration and Supplemental Declaration of Christopher Steskal.

Dated: October 4, 2007

Respectfully submitted,

FENWICK & WEST LLP

By: /s/ Christopher J. Steskal
Christopher J. Steskal

Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans

PROOF OF SERVICE

The undersigned declares as follows:

I am a citizen of the United States and employed in San Francisco County, State of California. I am over the age of eighteen years and not a party to the within-entitled action. My business address is Fenwick & West LLP, San Francisco California, 555 California Street, 12th Floor San Francisco, California 94104. On the date set forth below, I served a copy of the following document(s):

REPLY MEMORANDUM IN SUPPORT OF REQUEST FOR JUDICIAL NOTICE BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS

on the interested parties in the subject action by placing a true copy thereof as indicated below, addressed as follows:

Victor E. Zak
24 Oakmont Road
Newton Center, MA 02459

☒ **BY OVERNIGHT COURIER:** by placing the document(s) listed above in a sealed envelope with a prepaid shipping label for express delivery and causing such envelope to be transmitted to an overnight delivery service for delivery by the next business day in the ordinary course of business.

I declare under penalty of perjury under the laws of the State of California and the United States that the above is true and correct.

Date: October 4, 2007

/s/ Margaret E. Vertin
Margaret E. Vertin

FENWICK & WEST LLP
ATTORNEYS AT LAW
SAN FRANCISCO